UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,542	05/26/2005	Roger Petrus Gerebern Vandecruys	JANS-0086 / PRD2017USPCT	7079

45511 7590 11/09/2010

WOODCOCK WASHBURN LLP
CIRA CENTRE, 12TH FLOOR
2929 ARCH STREET
PHILADELPHIA, PA 19104-2891

EXAMINER	
VU, JAKE MINH	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficemonitor@woodcock.com

Office Action Summary	Application No.	Applicant(s)	
	10/536,542	VANDECRUYS ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-67* is/are pending in the application.

4a) Of the above claim(s) *43-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Argument filed on 10/22/2010.

- Claims 21-67 are pending in the instant application.
- Claims 43-67 have been previously withdrawn from consideration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 7,241,458 **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 7,037917 **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Claims 21-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of U.S. Patent No. 6,878,717 **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of copending Application No. 11/930,835 **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of copending Application No. 11/733,507 **are withdrawn** in view of the abandonment.

Claims 21-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of copending Application No. 11/204,513 **are withdrawn** in view of the abandonment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by CHEN et al (6,919,370; hereinafter "CHEN1") as evidence by FAIS et al (US 2008/0160106) and CASODEX (Drug Information at http://www.rxlist.com/casodex-drug.htm (2009)) **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-29, 31, 32, 34-42 are rejected under 35 U.S.C. 102(a,e) as being anticipated by CHEN1 et al (6,919,370; hereinafter "CHEN1") as evidence by FAIS et al (US 2008/0160106) and CASODEX (Drug Information at http://www.rxlist.com/casodex-drug.htm (2009)) **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Claims 21-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEN et al (US 6,828,301; hereinafter "CHEN2") in view of VERRECK et al (WO 01/22938) **are maintained** for reasons of record in the previous office action filed on 07/22/2010 and as discussed below.

Response to Arguments

Applicant argues that every example described by Chen1 is a liquid formulation, which the Examiner has admitted is clearly outside the scope of the solids and semisolids of the claims. Whereas the claimed invention requires the pharmaceutical composition to be a semi-solid or solid, Chen Formulation 1-13 are directed to liquid concentrate formulations. Moreover, while the Examiner uses Fais and Casodex to establish that cisplatin and bicalutamide are basic drug compounds that allegedly fulfill a limitation of the claims, at page 17 of the pending Action, the Examiner concedes that

"Chen1 does not teach an example having cisplatin or bicalutamide as the cancer drug." For at least these reasons, Chen1 cannot anticipate the present claims.

The Examiner finds this argument unpersuasive, because the prior art's teaching is not limited to examples. If this is so, then Applicant's claims should be limited to the Applicant's specification examples. In this instance case, CHEN1 specifically teach using other cancer drugs, such as cisplatin and bicalutamide (see col. 7, line 19-23), wherein CHEN1 states that formulations in the form of semi-solids and solids, such as lyophilized solid, are well know methods (see col. 16, lien 11-18).

Applicant argues that Chen1 is directed solely to formulations of paclitaxel, which is not a basic drug compound as required by the present claims. Despite the Examiner's attempts to point to various "laundry lists" of drug compounds, acids, polymers, bulking agents, etc., those of skill in the art know that paclitaxel can only be administered intravenously. Indeed, every formulation exemplified in Chen1 is to a liquid concentrate of paclitaxel.

The Examiner finds this argument unpersuasive, because CHEN1 specifically teaches "the paclitaxel solubilizers of the invention can be used to solubilize, distribute, and administer, but not limited to, other cancer and cancer-related pharmaceuticals, such as cisplatin" (see col. 7, line 19-22). Thus, there is strong motivation to use other cancer drugs, such as cisplatin.

Applicant argues that Chen1 is devoid of any examples of solid or semi-solid formulations. Citation to passing references of oral administration, tablets, or suspensions is disingenuous as no such formulations of paclitaxel are described in the

reference or are known in the art. As such, no one skilled in the art would have been motivated to modify the intravenous liquid formulations of Chen1 to arrive at the claimed solids and semi-solids.

The Examiner finds this argument unpersuasive, because lyophilization of cancer drugs used for injections are well known in the prior art, wherein the lyophilization prolong the stability of the drug. CHEN1 teaches solids, such as lyophilized solids, are well known in the art (see col. 16, line 11-18).

Applicant argues that the Examiner alleges that one skilled in the art would have substituted cisplatin or bicalutamide for the paclitaxel in the formulations described in Chen1 because he "would have expected success because Chen1 suggested using other cancer drugs, such as cisplatin or bicalutamide." No such suggestion is made in Chen1.

The Examiner finds this argument unpersuasive, because CHEN1 specifically teaches "the paclitaxel solubilizers of the invention can be used to solubilize, distribute, and administer, but not limited to, other cancer and cancer-related pharmaceuticals, such as cisplatin….bicalutamide" (see col. 7, line 19-22).

Applicant argues that Chen2, while describing surfactants generally, identifies that improved oral bioavailability is achieved with basic amines, not with Vitamin E TPGS and a physiologically tolerable water-soluble acid.

The Examiner finds this argument unpersuasive, because Chen2 teaches that improved dispersion and dissolution performance can be achieved by adding a surfactant to a pharmaceutical composition that comprises a drug compound and an

amine. Chen2 at col. 15, lines 45-60, col. 15, line 61-col. 16, line 28. Vitamin E TPGS is identified in Chen2 as a compound that has surfactant properties. Id. at col. 15, lines 45-60.

Applicant argues that Verreck fails to describe the use of any surfactants. Indeed, Verreck relies on water-soluble polymers to form particles having improved bioavailability.

The Examiner finds this argument unpersuasive, because VERRECK is a secondary reference to show that the prior art had known of a drug, such as 4-[[4-amino-5-bromo-6-(4-cyano-2,6-dimethylphenyloxy)-2-pyrimidinyl]amino]-benzonitrile. The primary reference CHEN2 teaches using surfactants such as Vitamin E.

Applicant argues that there is no suggestion or motivation in the cited art that would have led the skilled person to incorporate any surfactant, let alone the specific Vitamin E TPGS presently claimed, into the compositions described in Verreck.

The Examiner finds this argument unpersuasive, because as discussed in the previous office action, the person of ordinary skill in the art would have been motivated to make those modifications, because it would improve the dissolution and dispersion of the drug and both drugs are functional equivalent drugs used as antiviral drugs.

Applicant argues that the Declaration of Marcus Brewster that was submitted on September 16, 2009, Vitamin E TPGS gave surprisingly higher average supersaturation as compared to Cremophor RH40 and Polysorbate 20 with this effect being seen over a range of compounds having varying physicochemical properties. Declaration of Marcus Brewster at ¶ 4. Vitamin E TPGS also provided better stability of the formed

supersaturated solution than either Cremophor RH40 or Polysorbate 20. Id. at ¶ 5. Significantly, an oral bioavailability of 100% was achieved with a composition of the invention, compared to only 30% and 60% achieved with PEG400 and Cremophor RH40, respectively, Id. at ¶ 7. This surprising result is also unexpected.

The Examiner finds this argument unpersuasive, because CHEN1 specifically teaches Vitamin E-TPGS is better than Cremophor (see abstract; col. 3, line 57-67; and col. 11, line 48-66). Thus, it is not unexpected that Vitamin E-TPGS is better than Cremophor. Additionally, the primary reference uses Vitamin E-TPGS, thus, the primary reference would have the same result.

Applicant argues that each of the rejections in view of U.S. 7,241,458; U.S. 7,037,917; U.S. 6,878,717; and U.S. App. No. 11/930,835 is based on the disclosure of Chen2, which has been addressed above. For at least the reasons stated above, the disclosure of Chen2 does not support the allegations asserted by the Examiner and is insufficient to establish that the present claims are not patentably distinct over each of the cited art. Moreover, the Declaration of Marcus Brewster clearly establishes the unexpected results, and thus patentability of the claims.

The Examiner finds this argument unpersuasive, because as discussed above, CHEN2 does support the allegations asserted by the Examiner and the Declaration of Marcus Brewster does not clearly establishes the unexpected results, because the primary references were already using the Vitamin E-TGPS.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618